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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,466	08/07/2006	Ji Hoon Jeong	2236.0180000/JUK/SMW	4435

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WASHINGTON, DC 20005

EXAMINER

PITRAK, JENNIFER S

ART UNIT	PAPER NUMBER
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1635

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07/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,466	Applicant(s) JEONG ET AL.	
	Examiner JENNIFER PITRAK	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Remarks

Applicant's amendments and arguments filed 04/08/2008 have been considered.

Applicants have amended claims 1 and 5-8. Claims 9-13 are withdrawn. Applicants have indicated that claim 14 is pending, which is in contrast to the 10/2/2007 interview indicating that claim 14 was cancelled.

The Office regrets any confusion regarding the restriction requirement and the status of claim 14. Claim 14 is to a method of preparing a complex comprising the conjugate of any of claims 1-8, which is properly restricted from the composition of claims 1-8 as follows. The inventions listed as Group I (claims 1-8) and claim 14 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature shared between Group I and claim 14, a conjugate for gene transfer, does not contribute over the prior art as evidenced by the rejections set forth in the 01/08/2008 communication and in this communication. Group II (claims 9-13) and claim 14 will be eligible for rejoinder under 35 U.S.C. § 111 upon indication of allowable subject matter.

Claims 1-8 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 - WITHDRAWN

The amendment to claim 8 has obviated the rejection of claim 8 under 35 U.S.C. § 112. Therefore, the rejection is withdrawn

Claim Objections- NEW

Claim 1 is objected to because of the following informalities: the phrase, “via an acid-cleavable linkage” appears to be intended to refer to the means by which the claims oligonucleotide is linked to the hydrophilic polymer, but its placement in the claim is inappropriate for this intended reference. The phrase would more appropriately be placed at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102 – MAINTAINED

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tullis (1990, US Patent 4,904,582). This rejection is maintained for the reasons of record and as further described.

Tullis describes antisense oligonucleotide conjugates for transport across cellular membranes for modulating gene expression (abstract). Tullis teaches 20-nucleotide phosphodiester-linked antisense oligonucleotide conjugates (table 1, column 19) and further teaches oligonucleotide conjugates comprising acetal bond linking groups and PEG (column 4, lines 1-35). According to the website, www.newton.dep.anl.gov, a 20-nucleotide single-stranded DNA molecule has a molecular weight of approximately 6600 daltons (330 daltons per nucleotide). Thus, Tullis clearly anticipates the instant claims 1-7.

Response to arguments

Applicant argues that Tullis is not anticipatory of the claims because an ester bond is not acid-cleavable. The argument is moot in view of the amendment to claim 5 indicating that the linkage is selected from the group of acid cleavable linkages including an acetal bond and Tullis clearly teaches acetal bond linkages as described in the above rejection.

Claim Rejections - 35 USC § 103 - MAINTAINED

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raschella, *et al.* (1992, Cancer Research, v.52:4221-4226) and Tullis (1990, U.S. Patent 4,904,582). This rejection is maintained for the reasons of record.

Raschella, *et al.* teach *c-myb*-targeted antisense oligonucleotides and inhibition of *c-myb* expression with the antisense oligonucleotides (Fig. 4 and paragraph bridging p.4223-4224). The oligonucleotides were useful for inhibiting growth of tumor cells (abstract and Fig. 6). Raschella, *et al.* do not teach *c-myb* antisense oligonucleotides covalently linked to a hydrophilic polymer.

Tullis teaches oligonucleotides conjugated to PEG as described above (35 USC §102 rejection). Tullis teaches that the oligonucleotide-polymer conjugates are "more efficient in membrane transport, so as to be capable of crossing the membrane and effectively modulating a transcriptional system" (Abstract). At column 2, "Description of the Specific Embodiments", Tullis explains that "the amphiphilic nature of the product [oligonucleotide-polymer conjugates] aids in the transport of the conjugate across the cellular membrane and can provide additional advantages, such as increasing aqueous or liquid solubility of nucleic acid derivatives."

It would have been obvious to make a *c-myb*-targeted antisense oligonucleotide as taught by Raschella, *et al.* conjugated to PEG as taught by Tullis. One would have been motivated to make the antisense conjugate because Raschella, *et al.* demonstrated that targeting *c-myb* by antisense was useful for inhibiting tumor cell proliferation and Tullis taught that conjugating antisense oligonucleotides to polymers such as PEG provided more efficient transmembrane transport of the oligonucleotides. One would have a reasonable expectation of success in making the conjugates because Tullis demonstrated successful use of such conjugates for targeting the mouse Beta-globin mRNA (see 35 USC §102 rejection above). Thus, the instant claim 8 would have been obvious to one skilled in the art at the time of the instant application.

Response to arguments

Applicant argues that the references do not teach acid-cleavable linkages and therefore the references do not render the instant claims obvious. This argument is not persuasive because Tullis clearly teaches acetal bond linkages as described above in the rejection under 35 U.S.C. § 102(b).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak, PhD
Examiner
Art Unit 1635

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635